

## **REMARKS/ARGUMENTS**

The present amendment replies to an Office Action dated October 30, 2009. Claims 1-3, 7-12, 14, 15, and 18-29 are pending in the present application. In the Office Action, the Examiner rejected claims 1-3, 7-12, 14, 15, and 18-29 on various grounds. Claims 1, 12, and 23 have been amended and claims 30-32 added herein. The Applicant responds to each ground of rejection as subsequently recited herein. Reconsideration of this application and entry of this amendment is respectfully requested.

### **35 U.S.C. §103 Rejections**

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

A. Claims 12, 14, 15, and 18-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication).

The Applicant respectfully asserts that the *Miller* publication fails to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication fails to disclose, teach, or suggest:

A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

At most, the *Miller* publication discloses a medical device may comprise one or more layers comprising one or more distinct matrix polymer layers and, if desired, one or more

barrier layers. *See* paragraph [0052]. A barrier layer can be provided to control the rate of release of bioactive material or therapeutic agent from an adjacent layer, such a matrix polymer layer. *See* paragraph [0055]. First and second barrier layers (also annular in shape) are disposed on the exterior and interior surfaces, respectively, of the first annular layer. The first and second barrier layers that enclose the first annular layer are typically less permeable than the biocompatible matrix polymer and, thereby, control the rate of diffusion of the bioactive and optional therapeutic agents from the device to the external environment. *See* paragraph [0056]. The bioactive and/or therapeutic agent from the annular layer comprising the first matrix polymer composition would have to diffuse through its own barrier layer, into and through an annular layer comprising the second matrix polymer composition and through another barrier layer before reaching the external environment. *See* paragraph [0062]. Thus, the barrier layers of the *Miller* publication allow diffusion of the therapeutic agents through the barrier layers and do not cause the therapeutic agents to be released exclusively and sequentially as claimed. A therapeutic agent from an inner layer will diffuse through the outer layers and mix with therapeutic agents from the outer layers, so that the inner and outer layer drugs are administered simultaneously rather than sequentially.

In the Response to Arguments section on page 9 of the Office Action dated October 30, 2009, the Examiner asserted that the *Miller* publication teaches sequential release of therapeutic agents, providing the example that given a system where the rate of delivery of two different drugs contained in the same device is different and the slower releasing of the two is placed further from the device surface than the faster releasing drug, there is necessarily a period of time when the drugs are delivered sequentially (e.g. the period before the slow release drug has had enough time to reach the outermost surface). The Applicant respectfully disagrees. The *American Heritage® Dictionary of the English Language, Fourth Edition*, defines sequential as sequent, which is further defined as following in order or time; subsequent. In the Examiner's example, the two different drugs are released simultaneously, rather than sequentially, once the slower releasing of the two reaches the device surface. The release of the one drug does not follow the release of the other drug as required to meet the definition of sequential. The two drugs cannot be released both simultaneously and sequentially, as the terms are mutually exclusive.

Claims 14, 15, and 18-20 depend directly or indirectly from independent claim 12, and so include all the elements and limitations of independent claim 12. The Applicant therefore respectfully submits that dependent claims 14, 15, and 18-20 are allowable over the *Miller* publication for at least the same reasons as set forth above for independent claim 12.

Regarding claims 18 and 20, the *Miller* publication fails to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. See paragraph [0062].

Withdrawal of the rejection of claims 12, 14, 15, and 18-20 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication is respectfully requested.

B. Claims 1-3, 7-12, and 19-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al.* (the *Sirhan B* publication) in view of U.S. Patent Publication No. 2004/0002755 to Fischell, *et al.* (the *Fischell* publication).

The Applicant respectfully asserts that the *Miller* publication, the *Sirhan B* publication, and the *Fischell* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication fails to disclose, teach, or suggest:

A system for treating a vascular condition including therapeutic agents in each of the therapeutic coatings being released exclusively and sequentially upon the erosion of the overlying timing coating without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 1;

A coated stent wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents in each of the plurality of therapeutic coatings being released exclusively and sequentially without release of the therapeutic agents from other of the therapeutic coatings to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12; or

A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition including releasing the first therapeutic agent from the first therapeutic coating without releasing the second therapeutic agent from the second therapeutic coating, as recited in independent claim 23.

The *Sirhan B* publication and the *Fischell* publication also fail to disclose these limitations. At most, as discussed in Section A above, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer and fails to disclose sequential release of therapeutic agents as claimed.

Claims 2, 3, and 7-11, claims 19-22, and claims 24-29 depend directly or indirectly from independent claims 1, 12, and 23, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that dependent claims 2, 3, 7-11, 19-22, and 24-29 are allowable over the *Miller* publication, the *Sirhan B* publication, and the *Fischell* publication for at least the same reasons as set forth above for their respective independent claims.

Regarding claims 7, 9, and 27, the *Miller* publication fails to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. See paragraph [0062].

Withdrawal of the rejection of claims 1-3, 7-12, and 19-29 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication, the *Sirhan B* publication, and the *Fischell* publication is respectfully requested.

#### New Claims

Claims 30-32 have been added herein to more particularly point out and distinctly claim the Applicant's invention. Claims 30-32 are allowable over the cited references for at least the reasons discussed above for their respective independent claims 1, 12, and 23. No new matter has been added with the inclusion of claims 30-32, which are supported in the specification at least on pages 9 and 10, and in Figure 3.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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